

News from Ed Markey

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Rep. Markey Urges FDA Reform Lawmaker Queries Agency on Fast Track, Seeks More Post-Approval Monitoring

Washington, D.C. – Rep. Edward J. Markey (D-MA), a Senior Member of the Energy and Commerce Committee, today sent two letters to the Food and Drug Administration (FDA) questioning the agency's efforts to monitor the safety of approved drugs and its ability to keep the public safe from drugs with dangerous side effects.

"Every day we hear of another drug with dangerous side effects that went undetected and got the FDA seal of approval." Rep. Markey said, "The first thing that the FDA needs to do is to admit that it has failed as the watchdog of public safety then we can begin the work of reforming the agency."

Rep. Markey's first letter, sent on December 20, 2004 asked the FDA why they have not enforced the follow-up studies required by their fast-track approval system. This letter came in the wake of the AstraZeneca's announcement that their cancer drug Iressa (gefitinib), which was approved under the FDA's accelerated approval process, does not work.

Accelerated approval is an expedited process set up by the FDA to bring new drugs to treat serious or life-threatening diseases to market quickly. Using this process the FDA conditionally approves drugs on the basis of one small positive study provided that the company promises to conduct another study that confirms the results. AstraZeneca is an example of a company that followed the rules of fast track. They conducted their required follow up study and came forward with their negative results. Unfortunately many companies are not as responsible as AstraZeneca. According to an FDA report to Congress, as of September 30, 2003, companies had not initiated 65% of their required follow-up trials.

Rep. Markey said, "Fast Track was supposed to be a system of 'approval today, proof tomorrow;' but now it has simply become 'approval without the proof.' The problem is not a company such as AstraZeneca, which fulfilled its obligation to do a post-marketing study and found that its drug was not effective, but rather the scores of companies which break the rules by not doing the studies they promised to do when they received fast-track approval. Apparently the FDA has never exercised its authority to withdraw a product for failure to meet fast-track obligations. "

Rep. Markey's second letter, sent today, asked about the FDA's efforts to track the safety and effectiveness of approved drugs and collect important information on negative side effects. The current FDA approval process is only designed to look at the short term safety and effectiveness of drugs; it does not examine the long term effects of drugs in the marketplace, even when they know that the drugs will be used to treat chronic diseases.

Rep. Markey said, "The FDA's policy has really become one of Don't Ask, Don't Tell. The FDA doesn't ask for the long term side effects of drugs, and the drug companies don't tell what they have learned from their hidden studies. After a drug has been approved, companies have complete access to the market and no incentive to conduct any further studies. From the company's perspective the only thing that they can get from a post-

approval follow-up study is bad news. So unless the FDA forces them to conduct long term or confirmatory studies, most companies aren't going to conduct them.”

For more information on Rep. Markey's work on FDA reform and copies of the letters sent to the FDA, please go to <http://www.house.gov/markey/healthgen.htm>

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